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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,898	03/01/2002	Alexander Olek	81658A	4523

7590 06/10/2004

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EXAMINER	
SMITH, CAROLYN L	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 06/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/087,898	OLEK ET AL.	
	Examiner	Art Unit	
	Carolyn L Smith	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-42 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-42 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

Restriction/Election

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-31, drawn to a method for determining the biological effect and/or activity of at least one drug, chemical substance, and/or pharmaceutical composition, classified in class 424, subclass 9.1. If this Group is elected, then ALL of the below summarized EIGHT specie elections are also required.

II. Claims 32-34 and 36-38, drawn to a use of a method for determining at least one drug, chemical substance, and/or pharmaceutical composition that is biologically effective and/or active, classified in class 424, subclass 9.2. If this Group is elected, then ALL of the below summarized EIGHT specie elections are also required.

III. Claim 35, drawn to a biologically effective and/or active drug, chemical substance, and/or pharmaceutical composition, classified in class 424, subclass 1.11. If this Group is elected, then ALL of the below summarized EIGHT specie elections are also required.

IV. Claims 39-42, drawn to a method for the treatment of a disease and/or medical condition, classified in class 514, subclass 1. If this Group is elected, then ALL of the below summarized EIGHT specie elections are also required.

Specie Election Requirement for Groups I-IV:

This application contains claims directed to the following patentably distinct species of the claimed invention:

First Specie Election Requirement For All Groups:

Specie A: a biological sample A which is from at least one individual

Specie B: a biological sample A which is from a tissue

Specie C: a biological sample A which is from a cell

Specie D: a biological sample A which is from another biological material not listed above

Second Specie Election Requirement For All Groups:

Specie E: a biological sample B which is from at least one individual

Specie F: a biological sample B which is from a tissue

Specie G: a biological sample B which is from a cell

Specie H: a biological sample B which is from another biological material not listed above

Third Specie Election Requirement For All Groups:

Group I contains patentably distinct species, namely different means of obtaining the biological sample. If one of these Groups is elected, then please select one or all of the means species (see instant claim 2, for example) so that initial examination of this application may proceed.

Fourth Specie Election Requirement For All Groups:

Group I contains patentably distinct species, namely different types of biological sample. If one of these Groups is elected, then please select one or a combination of the biological sample type species (see instant claim 3, for example) so that initial examination of this application may proceed.

Fifth Specie Election Requirement For All Groups:

Specie I: biological material which is obtained from healthy individuals only

Specie J: biological material which is obtained from diseased individuals only

Specie K: biological material which is obtained from both healthy and diseased individuals

Sixth Specie Election Requirement For All Groups:

Specie L: samples taken before treatment only

Specie M: samples taken during treatment only

Specie N: samples taken after treatment only

Specie O: samples taken before, during, and after treatment

Seventh Specie Election Requirement For All Groups:

Group I contains patentably distinct species, namely different methylation DNA site locations. If one of these Groups is elected, then please select one or a combination of the methylation DNA regions species (see instant claim 13, for example) so that initial examination of this application may proceed.

Eighth Specie Election Requirement For All Groups:

Group I contains patentably distinct species, namely different unwanted side effects related with methylation relevant regions of genes. If one of these Groups is elected, then please select one or a combination of unwanted side effects species (see instant claim 14, for example) so that initial examination of this application may proceed.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed specie for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. The distinctness or independence of different sample locations, different sample types, different individuals of various health status, different methylation site locations, and different unwanted side effects is because each of these contain distinct entities with structures and functions that differ from other entities. The distinctness or independence of the various obtainment means is because each means involves different processes or steps from the other means. The distinctness or independence of the various treatment timings is because each represents different circumstances from the other timing sets. This divergent subject matter demonstrates the undue search burden if all species were to be initially examined.

Applicant is advised that a reply to this requirement must include an identification of the specie that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should an applicant traverse the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The inventions are distinct, each from the other because of the following reasons:

Inventions in Groups I-IV are related as product and the process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the biologically effective and/or active drug, chemical substance, and/or pharmaceutical composition of Group III may be utilized in distinct usages as needed in Group I for a method for determining the biological effect and/or activity of at least one drug, chemical substance, and/or pharmaceutical composition; in a use of a method for determining at least one drug, chemical substance, and/or pharmaceutical composition that is biologically effective and/or active as in Group II; in a method for the treatment of a disease and/or medical

condition as in Group IV; or alternatively; in a pharmaceutical composition lead computer modeling. All of these usages are distinct as requiring distinct and different functions thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were searched together.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (571) 272-0549.

June 7, 2004

ARDIN H. MARSCHEL
PRIMARY EXAMINER

6/8/04